

314 CMR 17.00 Industrial Wastewater Management for Biotechnology Operations

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17.01 Purpose

The purpose of 314 CMR 17.00 (Industrial Wastewater Management for Biotechnology Operations) is to provide uniform, minimum state regulatory standards applicable to certain biotechnology operations in Massachusetts that discharge industrial wastewater into a Publicly Owned Treatment Works with an EPA-approved Industrial Pretreatment Program. Biotechnology operations that meet the criteria for regulation under 314 CMR 17.00 and maintain compliance with this regulation are exempt from obtaining the Department permits and approvals specified in 314 CMR 17.04.

17.02 Definitions

For the purposes of 314 CMR 17.00, the following terms shall have the following meanings, unless the context clearly requires otherwise:

Alarmed Industrial Wastewater Treatment System (AIWTS) means a treatment system that is equipped with alarms to indicate potential malfunctions that could impact effluent limitation compliance, that annunciate at a location staffed during operating hours of the system, resulting in execution of an on-call system that causes an on-site response by an appropriately licensed operator of the subject industrial wastewater treatment system in a timely manner.

Biotechnology means the use of cellular and molecular processes from living systems to make or assist in making products.

Biotechnology Operation means any site or works, or portion of a larger site or works, where biotechnology processes are located and conducted, and from which industrial

wastewater is or will be generated, stored, treated, dewatered, refined, incinerated, reclaimed, stabilized, solidified, disposed, or otherwise processed.

Board means the Board of Registration of Operators of Wastewater Treatment Facilities established in M.G.L. c. 21, § 34A. The Board evaluates and certifies operators of wastewater treatment facilities pursuant to 257 CMR 2.00.

Clean untreated non-contact cooling water means water used to reduce temperature that does not come into direct contact with any biocide, raw material, intermediate product, waste product (other than heat), or finished product.

DEP or Department means the Massachusetts Department of Environmental Protection.

EPA means the United States Environmental Protection Agency

Existing Biotechnology Operation means an ongoing biotechnology operation that was operational prior to the promulgation date of 314 CMR 17.00.

Fully Automated Industrial Wastewater Treatment System (FAIWTS) means a treatment system that is equipped with treatment process controller(s), which are capable of initiating, conducting and completing wastewater treatment process automatically according to preset control parameters and treatment processes. In addition, an FAIWTS must be also capable of responding to any potential system malfunctions that could impact effluent compliance, including, but not limited to automatic system shutdown, switch the incoming flow to a temporary holding device or recirculating when necessary, sending appropriate alarm signals to a staffed location during the operating hours, or resulting in execution of an on-call system that notify a responsible operator in a timely manner.

Industrial Wastewater means any waste in liquid form resulting from any process of industry, trade or business, regardless of volume or pollutant content. Waste in liquid form consisting of only sewage is not industrial wastewater.

Industrial Wastewater Pretreatment means the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW.

Industrial Wastewater Treatment System or IWTS means any and all devices, processes and properties, real or personal, used in the collection, pumping, transmission, storage, treatment, disposal, recycling, reclamation or reuse of waterborne pollutants, but not including any works receiving a hazardous waste from off the site of the works for the purpose of treatment, storage or disposal, or holding tanks regulated under 314 CMR 17.00.

New Biotechnology Operation means a biotechnology operation that commences operation on or after the promulgation date of 314 CMR 17.00.

Pretreatment Facility means any site or works where the reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW.

Publicly Owned Treatment Works or POTW means any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature that is owned by a public entity. A POTW includes any sewers, pipes, or other conveyances only if they convey wastewater to a POTW providing treatment.

State Act means the Massachusetts Clean Waters Act, as amended, M.G.L. c. 21, §§ 26 through 53.

Water-borne animal bedding from cage washing operations means bedding waste entrained from cage washing operations. For the purposes of this regulation, water-borne animal bedding from cage washing operations does not include incidental quantities of cage washing solids that may be entrained in wastewater after the cages have been swept clean prior to washing operations.

17.03 Applicability

- (1) 314 CMR 17.00 shall apply to biotechnology operations that meet all of the following criteria:
 - (a) the biotechnology operation is used in making a medical device, drug, or biologic product derived in whole or in part from biotechnology, and one of the following applications or notices has been filed with FDA for such product: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, premarket approval application, or premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement);
 - (b) the biotechnology operation discharges industrial wastewater from such operations into a POTW with an Industrial Pretreatment Program, as defined in 40 C.F.R. 403, that has been approved by EPA; and
 - (c) the biotechnology operation has submitted a complete and timely *Registration and One-time Compliance Certification Statement* pursuant to 314 CMR 17.12(3) to the Department, the local sewer authority, and the Board.
- (2) 314 CMR 17.00 shall not apply to biotechnology operations that discharge industrial wastewater into a POTW of a local or regional sewer authority that

has received the Department's approval under 314 CMR 7.16 to administer sewer connection permits pursuant to the State Act.

- (3) 314 CMR 17.00 should be read together with 105 CMR 480 (Department of Public Health regulations on the Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste) and 248 CMR 2.13 (the Piping and Treatment of Special Waste section of the Uniform State Plumbing Code) that contain other requirements applicable to industrial wastewater discharges from biotechnology operations. No provision in 314 CMR 17.00 is intended to modify or affect the regulation of applicable wastes under 105 CMR 480 and 248 CMR 2.13.

17.04 Exemptions

- (1) A biotechnology operation that meets the applicability criteria in 314 CMR 17.03(1) and is in compliance with 314 CMR 17.00 is exempt from the following Department permits and approvals:
 - (a) Department approval of the treatment works under M.G.L. c. 111, §17;
 - (b) Department approval of major physical modifications of treatment works under 314 CMR 12.03(1);
 - (c) Department approval of a change in the characteristics of a discharge to a treatment works in excess of that specified under any existing approval by the Department under 314 CMR 12.03(2);
 - (d) Department approval of treatment plans under 314 CMR 12.03(4); and
 - (e) Department approval of a staffing plan for the treatment works under 314 CMR 12.04(3).
- (2) The Board's regulations at 257 CMR 2.04(2) provides that persons who manage, operate and maintain a wastewater treatment facility in compliance with the grading of wastewater treatment facilities provisions in 314 CMR 17.06 and the certified operator staffing requirements in 314 CMR 17.07 are exempt from obtaining approval from the Board of Registration of Operators of Wastewater Treatment Facilities for facility grading and certified operator staffing plans. **[Note: inclusion of this informational provision is predicated on the Board amending its regulations on or before the date that 314 CMR 17.00 is promulgated.]**

17.05 General Requirements

The following general requirements apply to a biotechnology operation regulated under 314 CMR 17.00:

- (1) The discharge of water-borne animal bedding from cage washing operations to a POTW is prohibited.

- (2) A biotechnology operation shall not discharge clean untreated non-contact cooling water to a POTW, unless the local sewer authority expressly authorizes such discharge.
- (3) A new biotechnology operation shall have an industrial wastewater treatment system or a major system upgrade in place that has been constructed in accordance with engineering plans stamped and signed by a Massachusetts Registered Professional Engineer.
- (4) An existing biotechnology operation shall have an industrial wastewater treatment system or a major system upgrade in place that has been constructed in accordance with engineering plans stamped and signed by a Massachusetts Registered Professional Engineer. As an alternative, an existing biotechnology operation may have the existing industrial wastewater treatment system inspected and evaluated by a Massachusetts Registered Professional Engineer, provided that any deficiencies identified during such inspection and evaluation shall be documented in a report to the Department and the local sewer authority and corrected within 30 days of the submittal of the evaluation report.

17.06 Grading of Industrial Wastewater Treatment Systems (IWTS)

- (1) Any biotechnology operation that uses an IWTS consisting of a single or dual stage pH adjustment treatment system only shall be exempt from the Department treatment plant plan approval requirements in 314 CMR 12.03(4) and shall be graded as a Grade 1I (one, industrial) system.
- (2) Any biotechnology operation that uses an IWTS consisting of only one of the following processes for industrial treatment, with or without a single or dual stage pH adjustment treatment system, shall be exempt from treatment plant plan approval requirements in 314 CMR 12.03(4) and shall be graded as a Grade 2I (two, industrial) system:
 - (a) cartridge filtration;
 - (b) cartridge metallic ion replacement;
 - (c) cartridge single or dual stage ion exchange;
 - (d) reverse osmosis;
 - (e) ultra filtration system; or
 - (f) carbon absorption.
- (3) All other IWTS configurations shall be approved and graded in accordance with the provisions of 257 CMR 2.00 and 314 CMR 12.00.

¹ TTO Limit is the sum of the concentration of all Toxic Chemical concentrations that may be in the user's waste stream.

- (4) Any sterilization, disinfection, deactivation, or other process or system used by a biotechnology operation solely to render living organisms nonviable prior to discharge to a sewer system shall not be considered a treatment process that is subject to requirements for the grading and operation of industrial wastewater treatment systems under 314 CMR 17.00, 314 CMR 12.00, and 257 CMR 2.00.

17.07 Staffing Requirements for Industrial Wastewater Treatment Systems (IWTS)

- (1) A biotechnology operation without an IWTS is not subject to the requirements of 314 CMR 17.09.

- (2) A biotechnology operation shall comply with the following staffing requirements:

(a) Operator Grading

- i. Each biotechnology operation shall have at least one chief operator and one assistant chief operator. However, the use of additional licensed operators is recommended by the Department to assure adequate staffing in the absence of the chief operator and/or the assistant chief operator.
- ii. For Grade 1I (one, industrial) systems, as defined in 257 CMR 2.11, the chief operator and assistant chief operator of the IWTS shall be Massachusetts certified wastewater treatment plant operators with a grade equal to or greater than Grade 1I (one, industrial).
- iii. For Grade 2I (two, industrial) systems, the chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal to or greater than Grade 2I (two, industrial). The assistant chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal or greater than a Grade 1I (one, industrial).
- iv. For a biotechnology operation with an IWTS graded at a level greater than 2I (two, industrial) and less than a Grade 5 (five), the chief operator of the IWTS shall be a Massachusetts certified wastewater treatment plant operator with a grade equal to or greater than the grade of the IWTS. The assistant chief shall, at a minimum, be a Massachusetts certified wastewater treatment plant operator with a grade equal to, but not less than, one grade below the grade of the treatment system.

The following table summarizes 17.09(2)(a) i through iv.

<u>IWTS Grade</u>	<u>Required Minimum Chief Operator Certification Level</u>	<u>Required Minimum Assistant Chief Operator Certification Level</u>
1I	1I	1I
2I	2I	1I
>2I and < 5	> or = IWTS Grade	>or = (IWTS Grade) - 1

- (b) The owner or operator of any IWTS shall prepare a staffing plan in accordance with 314 CMR 12.04(3). A copy of the staffing plan shall be kept at the site of the IWTS and shall be made available for review by the Department and the local sewer authority upon request.
- (c) The owner or operator of any biotechnology operation with an IWTS shall provide adequate certified operator personnel to ensure that the IWTS is properly operated, maintained, and in compliance with applicable effluent limits at all times.
 - i. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for an IWTS that is not alarmed and is not automated shall mean:
 - a. For a Grade 1I (one, industrial) IWTS that is operated eight (8) hours or more per calendar day, a certified operator at least equal to the IWTS grade shall be present during at least 8 hours per calendar day that the treatment system is operational;
 - b. For a Grade 2I (two, industrial) IWTS or higher that is operated more than eight (8) hours per calendar day, a certified operator at least equal to the IWTS grade shall be present at least 8 hours per calendar day that the system is operational and, at a minimum, a certified operator no more than one grade lower than the IWTS grade shall be present during all operations;
 - c. For an IWTS that is operated less than 8 hours per calendar day, a certified operator at least equal to the IWTS grade shall be present during all operations; and
 - ii. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for an alarmed IWTS, regardless of the grade, shall mean that a certified operator at least equal to the IWTS grade shall visit and monitor the treatment system daily and shall be available to address problems any time during treatment system operation.
 - iii. For the purposes of 314 CMR 17.09(2)(c), adequate certified operator personnel for a fully automated IWTS shall mean
 - a. For a Grade 1I (one, industrial) fully automated IWTS, a certified operator at least equal to the IWTS grade shall visit and monitor the system twice weekly, preferably on Monday and Friday, and shall be available to address problems any time during treatment system operation.
 - b. For a Grade 2I (two, industrial) fully automated IWTS, a certified operator at least equal to the IWTS grade shall visit and monitor the treatment system daily and shall be available to address problems any time during treatment system operation.

- iv. A biotechnology operation may request the Department's approval pursuant to 314 CMR 12.04(3) of a staffing plan that differ from the requirements in 310 CMR 17.09(3)(c)i.-iv. above.

The following table summarizes 17.09(2)(c) i through vi.

<u>Facility Grade or Type</u>	<u>Duration of Facility Treatment System Operation</u>	<u>Required Operator Certification Level</u>	<u>Minimum Time the Certified Operator Must be Present at the Treatment System</u>
1I	> or = 8 hours	> or = Facility Grade	8 Hours
> or = 2I	> or = 8 Hours	> or = Facility Grade	8 Hours
> or = 2I	> or = 8 Hours	> or = Grade (Facility) - 1	8 Hours
Any Grade	< 8 Hours	> or = Facility Grade	At all Times the IWTS is Operational
Alarmed IWTS of Any Grade	Any Amount of Operational Time	> or = Facility Grade	Daily Visits and On-call During All Operations
1I Fully Automated IWTS	Any Amount of Operational Time	> or = Facility Grade	2 Visits per Week, Monday & Friday Preferred and On-call During All Operations
2I Fully Automated IWTS	Any Amount of Operational Time	> or = Facility Grade	Daily Visits and On-call During All Operations

- (d) For non automated Grade 1I or 2I (one or two, industrial) IWTS, the following activities shall be done by, or under the direct supervision of an appropriately licensed operator of the IWTS:
- chemical preparation;
 - equipment maintenance and calibration;
 - instrumentation adjustments;
 - preventive maintenance tasks identified in the IWTS Operations and Maintenance (O&M) Manual required under 314 CMR 17.10;
 - corrective maintenance tasks necessary to assure proper IWTS operation; and
 - any sampling events exclusive of automatic pH monitoring.

17.8 Operation and Maintenance Requirements for Industrial Wastewater Treatment Systems (IWTS)

- (1) The owner or operator of a biotechnology operation shall prepare an operation and maintenance (O&M) manual for the IWTS to be used by its operations personnel. The matters to be adequately addressed in the O&M manual shall include but not be limited to:
 - (a) Procedures for the IWTS, wastewater collection, treatment operations, equipment cleaning, calibration, equipment replacement, emergencies, chemical make-up, personnel, and equipment safety;
 - (b) Procedures for documentation of all maintenance, calibration, and effluent analyses; and
 - (c) Training programs regarding the biotechnology operation and the operation and maintenance of the IWTS.
- (2) A copy of the O&M manual shall be kept on-site and made available for review by the Department and the local sewer authority upon request.

17.9 Recordkeeping for the Industrial Wastewater Treatment Systems (IWTS)

- (1) The following documents shall be maintained at the biotechnology operation and be made available for review by the Department and the local sewer authority upon request for as long as the IWTS is in operation, regardless of any change of ownership:
 - (a) All permits required by federal, state, and local authorities;
 - (b) The current facility plan for the treatment system and any related engineering evaluation reports;
 - (c) As built construction plans of the treatment system;
 - (d) Up to date equipment specifications for the treatment system; and
 - (e) The current operation and maintenance manual.
- (2) The following documents shall be maintained at the biotechnology operation for a minimum of three (3) years and shall be made available to the Department and the local sewer authority upon request:
 - (1) Operation and maintenance documents, including but not limited to a daily operation log, a routine inspection log, an equipment maintenance log, and a chemical and supply inventory;
 - (2) Sampling and analysis documents, including but not limited to chain of custody documents, raw data, quality assurance and quality control results, and analytical reports; and
 - (3) Staff training documents, including but not limited to, dates of training, names of instructors and trainees, training material, training results (e.g., test scores and pass rates), and the instructor's comments on each trainee.

17.10 Reporting

Biotechnology operations subject to 314 CMR 17.00 shall file a *Registration and One-time Compliance Certification Statement* with the Department, the local sewer authority, and the Board.

- (1) For an existing biotechnology operation, the Report shall be filed within 90 days from the date of promulgation of 314 CMR 17.00.
- (2) For a new biotechnology operation, the Report shall be filed 30 days prior to any discharge of industrial wastewater to the POTW.
- (3) The Registration shall include but not be limited to the following information and shall be on a form as prescribed by the Department:

(a)Registration Information. For the purpose of notifying the Department, the local sewer authority, and the Board that a biotechnology operation is being regulated under 314 CMR 17.00, the biotechnology operation shall, at a minimum, provide the following registration information:

- i. The name and location of the biotechnology operation and related contact information;
- ii. A description of the biotechnology operation;
- iii. A schematic diagram of the IWTS used by the biotechnology operation and the grade of the IWTS; and
- iv. The number, identity, and grades of certified wastewater treatment facility operators used by the biotechnology operation.

(b) A list of those toxic chemicals, contained in 360 CMR 10.00, Appendices A and B, that are used at the biotechnology operation and have the potential to be discharged to the POTW.

- i. In any year in which a new toxic chemical, contained in 360 CMR 10.00, Appendices A and B, is used that has the potential to be discharged to the POTW, an updated list of toxic chemicals shall be provided to the Department on or before December 31 of that year.

(c)One-time Compliance Certification Statement. An authorized representative of the biotechnology operation shall make and include the following certification in the Report:

“I, [name of authorized representative], attest under the pains and penalty of perjury:

- i. that I personally examined and am familiar with the information contained in this submittal;
- ii. that based on my inquiry of those individuals responsible for obtaining the information, the information contained in this submittal is to the best of my knowledge, true, accurate, and complete;

iii. that I have reviewed and understand the requirements of 314 CMR 17.00 and that the [name of the biotechnology operation] meets the criteria for regulation under 314 CMR 17.03(1);

iv. that personnel of the biotechnology operation responsible for assuring compliance with the requirements of 314 CMR 17.00 have also reviewed and understand the requirements of this regulation;v. that systems to maintain compliance with 314 CMR 17.00 are in place at the biotechnology operation and will be maintained; and

vi. that I am fully authorized to make this attestation on behalf of the biotechnology operation, and that I am aware that there are significant penalties, including but not limited to, possible fines and imprisonment for submitting false, inaccurate, or incomplete information.”

17.11 Enforcement

- (1) The Department may enforce the provisions of 314 CMR 17.00, through the issuance of orders and/or civil administrative penalties, pursuant to its authority under M.G.L. c. 21, §§ 26 through 53, M.G.L. c. 21A, § 16 and 310 CMR 5.00.
- (2) The Department may require any biotechnology operation to obtain the permits and plan approvals for activities that are otherwise exempt under 314 CMR 17.00 from such permits and plan approvals if the Department determines that such action is necessary to protect the public health, safety, and the environment.
- (3) The Department may require any person to provide information as the Department may reasonably require to determine whether that person is subject to M.G.L. c. 21, §§ 26 through 53 or 314 CMR 17.00 or has violated M.G.L. c. 21, §§ 26 through 53 or 314 CMR 17.00.

Regulatory Authority

314 CMR 17.00 is promulgated pursuant to the Department’s authority under M.G.L. c. 21, §§ 26 through 53.

257 CMR 2.00 Certification of Operators of Wastewater Treatment Facilities

1. The existing paragraph in 2.04 should be numbered subsection (1).
2. A new subsection (2) will be added:
 - (2) Persons who manage, operate and maintain a wastewater treatment facility in compliance with the grading of wastewater treatment facilities provisions in 314 CMR 17.06 and the certified operator staffing requirements in 314 CMR 17.07 (the Department of Environmental Protection's Industrial Wastewater Management and Discharge Requirements for Biotechnology Facilities) are exempt from obtaining Board approval for facility grading and certified operator staffing plans.